K122975

510(k) Summary

DEC 20 2012

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Date Prepared: September 25, 2012

DEVICE INFORMATION

Trade/Proprietary Name: G.K.S. Prime Flex CR Total Knee System
Common Name: Total Knee Prosthesis
Classification Name: Knee joint, patellofemorotibial metal/polymer/metal Semi-constrained cemented prosthesis, 21 CFR 888.3560

Main Predicate: NexGen® Complete Knee Solution

K023211 NexGen® Complete Knee Solution Cruciate Retaining (CR) – Flex (Zimmer)

K072281 NexGen® Prolong™ All Poly Patella (Zimmer)

K933785 NexGen® Complete Knee Solution (Zimmer)

Other Predicates

K081023 Evolis Total Knee System (Medacta International)

K041825 Genesis II Deep Flexion Cruciate Retaining Articular Insert (Smith and Nephew)

K110950 Consensus Knee System, Consensus Orthopedics (based on K932837)

K971189 P.F.C Sigma Knee System (Johnson & Johnson Professional, Inc., now DePuy Orthopedics)

Product Description:
The GKS Prime Flex CR Total Knee System is a tricompartmental fixed bearing total knee prosthesis comprised of femoral, patellar, and tibial components with ultra-high molecular weight polyethylene articular inserts. The femoral components are offered in left and right versions in eight sizes each. The tibial baseplate components are offered in seven sizes offered in two styles: Universal which will work with either left or right knees and Anatomic which provides components anatomically shaped for left and right knees. The keel has a cylindrical body with two stabilizing wings and allows for future use of extension stems.[1] The tibial inserts fit into the tibial baseplates by a snap-in mechanism. The cruciate retaining tibial inserts are offered in seven sizes, each size in four thicknesses from 10 mm to 18 mm. These tibial inserts work with the universal design or either the left or right anatomic version. The patella is offered in four sizes from 32 to 38 mm. The devices are for cemented use only.

The bone opposing surfaces are not coated but have their surfaces roughened by sand blasting.

The tibial baseplates come with threaded plugs for bone screw holes as no bone screws are available with this system. A distal plug for a future extension stem is also provided.

The GKS Prime Flex CR Total Knee System femoral components are made of Cobalt Chromium Molybdenum (CoCrMo) according to ISO 5832-4. Tibial baseplate components, threaded plugs for screw holes, and distal plug are made of titanium alloy (Ti6-Al4-V) according to ISO 5832-3. Tibial inserts and patellar components are made of standard ultra-high molecular weight polyethylene (UHMWPE) according to ISO 5834-1/2.

Indications for Use:
G.K.S. PRIME FLEX CR is indicated for use in patients with severely painful and disabled joints due to:

- Osteoarthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis
- Failed osteotomies
- Avascular necrosis of femoral condyle
- Post traumatic loss of joint configuration
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability
- Primary implantation failure if there is sufficient bone

The device is intended for cemented use only.

[1] Extension stems are not part of this submission

Comparison to Predicate Devices

The GKS Prime Flex CR Total Knee System has the same intended use as all of the predicate devices. It has very similar indications for use as its main predicate, the NexGen® Complete Knee Solution. The GKS Prime Flex CR Total Knee System components are made of the same materials for each component as one or more of the predicate devices. The GKS Prime Flex CR Total Knee System components' design and technological characteristics are similar to one or more of the predicate devices.

Performance Testing (Nonclinical and/or clinical)

No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Nonclinical performance testing of the GKS Prime Flex CR Total Knee System was conducted in accordance with the applicable standards and FDA guidance documents, specifically Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial Metal/Polymer Porous Coated Uncemented Prostheses: Guidance for Industry and FDA..

The GKS Prime Flex CR Total Knee System was tested as part of design verification to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the applicable standards and guidance. The testing was conducted on the worst case component size and option/design. Functional testing, according to the above cited FDA guidance, included fatigue testing of the tibial base plate, constraint and contact pressure of the patella-femoral and femoro-tibial interfaces, and modular connections of tibial inserts to tibial baseplates. The results of the GKS Prime Flex CR testing were compared to published results of similar testing of predicate devices. The testing met all acceptance criteria and verifies that performance of the GKS Prime Flex CR Total Knee System is substantially equivalent to the predicate devices.

Clinical data and conclusions are not needed for this device.

Conclusion:

The data and information provided in this submission support the conclusion that the GKS Prime Flex CR Total Knee System is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2012

Permedica, S.p.A.
% NJK & Associates
Ms. Natalie J. Kennel
RA Consultant
13721 Via Tres Vista
San Diego, California 92129

Re: K122975
Trade/Device Name: GKS Prime Flex CR Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Codes: JWH
Dated: September 25, 2012
Received: September 26, 2012

Dear Ms. Kennel:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosures) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122975

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The device is intended for cemented use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey Hanley

For Division of Orthopaedic Devices